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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,402	08/14/2001	Tsuneyuki Nagae	PO7336US00/LRP	8312

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,402	NAGAE ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 13, 2006 has been entered. Claims 3-4 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 3-4 rejected under 35 U.S.C. 103(a) as being unpatentable over Nyamekye et al (Circulation 1995; 91:417-425) in view of Nariciso Jr, US Patent 5,298,018 and Aizaw et al US Patent 5,308,861.

3. The scope of the pending claims is essentially directed to a method of performing photodynamic therapy to reduce restenosis post an angioplasty procedure comprising administering Npe6 intravenously to a patient who has undergone an angioplasty procedure and subjecting the patient at a point of 0.5-6 hours after administration of Npe6 to a local irradiation of laser light of 664 nm wavelength at laser fluence of 1-10 J/cm2. Examiner adds that the delivery process instantly described in claim 3 is inherent to the PCTA procedure and those described by the cited prior art.

4. For example, Narciso teaches that photodynamic theapy during PCTA procedure to limit restenosis of a blood vessel intima subject to a smooth cell proliferation (see abstract). Narciso specifically explains that the use of a photodynamic agent can be during, before or after a PCTA procedure (see col 2, lines 6-65). Narciso also suggests Npe6 to be a suitable photosensitizer for such treatment (see col 7, table 1, under class Phorobides). Since Narciso teaches the use of photodynamic therapy during a PCTA procedure, all method steps of the instant claims are also inherently disclosed.

5. Nyamekye teaches methods of administering photodynamic therapy to a mammal for inhibiting the development of intimal hyperplasia (restenosis) caused by a vascular intervention procedure such as balloon angioplasty (see abstract; pages 3-5). Nyamekye clearly teaches inhibiting restenosis in vessels of rats that have undergone a balloon angioplasty and have experienced stretch injury of arorta. (sees page 8-9). Such teaching meets the instant limitation of suppressing thickening of vascular intima of blood vessels.

Nyamekeye uses 5-amiono-levulinic acid as the photosensitizer and applies a laser radiation of about 50 J/cm2 at 630 nm wavelength for a period of 30-90 minutes after administration of the photosensitizer (see page 3-5, under the heading "methods and material"). Nyamekyes administers his photodynamic methodology to rats after they have undergone an angioplasty procedure. Nyamekyes suggests photodynamic therapy given at suitable time after angioplasty will eliminate the expected restenosis post an angioplasty procedure (see page 13, last para). Nyamekye fails to explicitly teach the use of mono-L-aspartylchlorin e6 at a laser wavelength of 667 nm and a laser density of 1-10 J/cm2.

6. Narciso teaches that photodynamic theapy is also effective during PCTA procedure to limit restenosis of a blood vessel intima subject to a smooth cell proliferation (see abstract). Narciso specifically explains that the use of a photodynamic agent can be during, before or after a PCTA procedure (see col 2, lines 20-35). Narciso also suggests Npe6 to be a suitable photosensitizer for such treatment (see col 7, table 1, under class Phorobides). Narciso teaches the activation wavelength of Npe6 to be

about 660nm and describes suitable dosing. (see table 1). Narciso uses a light dose of 20J/cm2 (see col 8, lines 63-69; col 9, lines 19-34).. Narciso teaches that the timing of light delivery following sensitization is about 32 hours and that determination of such parameter is a function of the pharmacokinetics of individual photosensitizers (see col 9, lines 1-55). Since Narcisco teaches the use of photodynamic therapy during a PCTA procedure, all method steps of the instant claims are also inherently disclosed.

7. Aizawa is merely used to show that the local administration of Npe6 during an intravascular catherization procedure is well described in the art for its therapeutic effects (see col 21, line 60-col 26, line 20). Aizawa also teaches the same doses of Npe6 to produce photosensitizing effects. Aizawa fails to specifically describe the same method during a Percutaneous Transuluminal Coronary Angioplasty procedure (PCTA).

8. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the ALA of Nyamekye with another photosensitizer such as Npe6 of Narciso and Aizawa and further improve the clinical outcome and prognosis of patients who undergo angioplasty procedures of Narciso or Nyamekye. One of ordinary skill in the art would have been motivated to use Npe6 in place of ALA, because as suggested by all cited references any suitable photosensitizer would have provided the same clinical results and are viewed to be art recognized functional equivalents in preventing restenosis secondary to an angioplasty procedure.

Finally, optimizing the laser wavelengths and density is a matter of routine experimentation and as described by Narciso a function of individual sensitizers.

9. Claims 3-4 rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins (British Journal of Surgery 1999, 86, 1258-1263) in view of Nariciso Jr, US Patent 5,298,018 and Aizaw et al US Patent 5,308,861.

10. Jenkins teaches the use of photodynamic therapy in humans to reduce neointimal hyperplasia after a balloon induced injury angioplasty (see abstract; entire paper). Jenkins teachings are similar to Nyamekye except that Jenkins administers his methodologies to human subjects instead of rats. Jenkins also predicts the success of photodynamic therapy in reducing restenosis following angioplasty (see page 1262).

Jenkins fails to explicitly teach the use of mono-L-aspartylchlorin e6 at a laser wavelength of 667 nm and a laser density of 1-10 J/cm2.

11. The teachings of Narciso and Aizawa are described above.

12. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the ALA of Jenkins with Npe6 of Narciso or Aizawa and improve the outcome of angioplasty procedures such PCTA procedure of Narciso or balloon angioplasty of Jenkins and further optimize the laser wavelength and density of such photosensitizer agent. One of ordinary skill in the art would have been motivated to use Npe6 in place of ALA, because as suggested by all references all photosensitizers, would have provided the same results and are viewed to be art recognized functional equivalents in preventing restenosis secondary to an angioplasty procedure.

Response to Arguments

13. Applicant's arguments, filed on February 13, 2006 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

The Declaration under 37 CFR 1.132 filed by Dr. Nagae was sufficient to overcome the rejection of claims 3-4 based upon Aizawa in view of Narciso. However, the claims are now subject to a new grounds of rejection and the Declaration is not deemed to overcome the new grounds of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER